

Practice Hospital Bed Safety

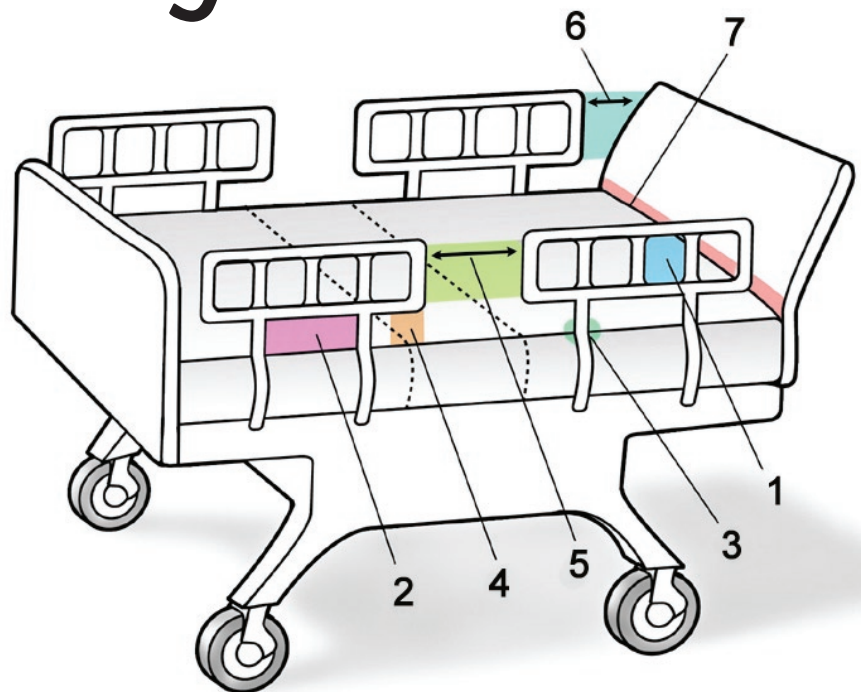
“Hospital beds are found in nearly all patient care settings or environments,” says Joan Ferlo Todd, RN, a senior nurse-consultant at the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH). “They are used not only in hospitals, but also in outpatient care centers, long-term care facilities, and in private homes.”

CDRH reports that about 2.5 million hospital beds are in use in the United States. The center regulates these beds as medical devices.

“Many of today’s hospital bed models are quite complex. Patients and health care professionals should understand how to use them properly, and manufacturers must provide adequate instructions for use,” says Todd, who works in CDRH’s Office of Surveillance and Biometrics.

Beware of Entrapment

The main risk is entrapment, which occurs when a patient is caught in spaces in or around the bed rail, mattress, or bed frame. Entrapped individuals can become strangled.



Hospital Bed Entrapment Zones

An FDA guidance characterizes the head, neck, and chest as key body parts at risk of entrapment, and identifies seven potential “zones of entrapment” where special care is required:

1. within the rail
2. under the rail, between the rail supports or next to a single rail support
3. between the rail and the mattress
4. between the rail, at the ends of the rail
5. between split bed rails
6. between the end of the rail and the side edge of the head or foot board
7. between the head or foot board and the mattress end

It is important to view the hospital bed as a system. Not all mattresses or bed rails are suitable with any given bed frame.

"Patient entrapment is uncommon," says Todd, "but when it occurs, it's often fatal."

Between 1985 and 2009, FDA received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds. The reports included 480 deaths, 138 nonfatal injuries, and 185 cases where staff intervened to prevent an injury. Most of the affected patients were frail, elderly, or confused.

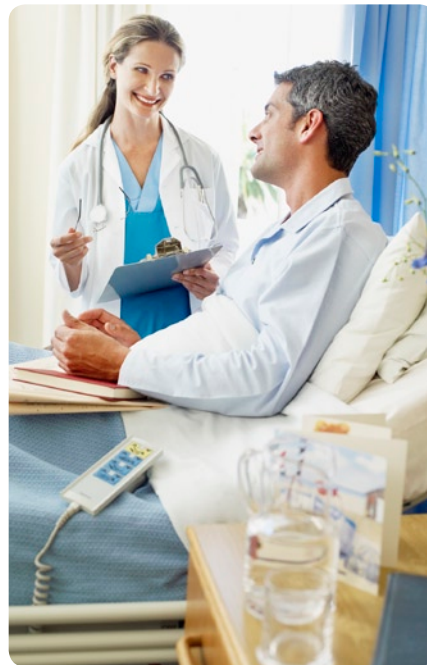
"Not all patients are at risk for entrapment, and not all hospital beds pose an entrapment risk," says Todd. "But health care facilities, as well as patient caregivers, are urged to take a careful look at hospital beds. They need to determine if there are large openings that present an entrapment risk, and to take steps to minimize this risk."

Any type of rail or grab bar attached to a bed, as well as the fit of the bed mattress, should be assessed for entrapment risks, she adds. "It is important to view the hospital bed as a system," she says. "Not all mattresses or bed rails are suitable with any given bed frame."

Guidance

FDA regulates hospital beds through post-market activities such as analyzing reports of product problems and adverse events, says Todd. "Although the agency does not regulate the design of the beds, it offers safety guidance to industry."

FDA is a member of the Hospital Bed Safety Workgroup (HBSW), a partnership among the medical bed industry, national health care organi-



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zations, patient advocacy groups, and federal agencies.

In 2006, FDA with collaboration from HBSW issued "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment," recommendations for manufacturers of new hospital beds and for facilities with existing beds, including hospitals, nursing homes, and private homes.

"The guidance may also be used by health care facilities," says Jay A. Rachlin, director of CDRH's Division of Health Communication in the Office of Communication, Education, and Radiation Programs. "It offers useful information for health care facility staff."

Rachlin says the guidance, along with other educational products from

FDA and the HBSW, have improved patient safety. "Manufacturers have redesigned their bed frames and their side rails to reduce the risk of entrapment."

Entrapment Zones

The guidance characterizes the head, neck, and chest as key body parts at risk of entrapment. It also identifies these seven potential "zones of entrapment" in hospital beds:

1. within the rail
2. under the rail, between the rail supports or next to a single rail support
3. between the rail and the mattress
4. between the rail, at the ends of the rail
5. between split bed rails
6. between the end of the rail and the side edge of the head or foot board
7. between the head or foot board and the mattress end

Rachlin says that proper fitting rails can be useful. However, health care professionals and patients need to assess whether rails are necessary in each instance. "In addition to entrapment, there are other potential hazards associated with bed rail use, including serious injuries from falls when patients climb over rails, and having patients feel isolated or unnecessarily restricted," he says.

Fire Prevention

Fire is a rare safety risk associated with motorized hospital beds. "Fires are due mostly to a lack of maintenance," says Todd. "There are electri-

Some hospital beds used at home may require patient or caregiver training.

cal shorts due to frayed or strained wires, motors overheat, or dust or other materials from the hospital fall into the motor casing."

She suggests these steps to cut the risk of fire incidents:

- Inspect the bed's power cord for damage.
- Don't connect the bed's power cord to an extension cord or to a multiple-outlet strip.
- Inspect the floor beneath the bed for buildup of dust and lint, which could clog the motor.
- Inspect the bed control panel covering for signs of damage where liquids could leak in.
- Check equipment for signs of overheating or physical damage.
- Keep linens and clothes away from power sources.

Home Use

Todd says there have been very few reports of safety incidents with hospital beds used in private residences. "This may represent underreporting by consumers," she says. "The reporting system for these incidents is set up for health care facilities, but consumers and home patients can still report medical device incidents to FDA through its MedWatch program."

She adds that hospital beds used at patients' homes are usually prescribed devices. "They're not required to be prescribed, but the beds are usually very expensive to rent or buy, and most patients get them for home through health plans."

It is important to ask that the bed meet the guidelines in the FDA guidance to reduce the risk of entrapment. Some hospital beds used at home may require patient or caregiver training,

Todd says. "It depends on the complexity of the bed."

Safety Tips

CDRH offers the following safety tips for home use of hospital beds:

- Check the motors, especially for dust and debris.
- Ensure that each component—the bed frame, mattress, rails, and any added accessories—properly fits together. Make sure the mattress is the correct size for the bed frame so unsafe gaps are not present. If you see an opening let a health care professional know or call the manufacturer.
- When in doubt, consult the bed frame manufacturer to determine if a component or accessory is compatible with your bed frame.
- Use rails cautiously. Patients should not try to climb around or over the rails to get out of bed.

What is a Hospital Bed?


Todd says that there is no standard definition for hospital beds, a fact that consumers shopping for such a bed need to be aware of.

"A bed becomes a hospital bed when it meets the requirements for being a medical device," she says.

CDRH defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."

"There are beds sold in retail stores that don't meet the definition of medical devices under the law, but which may have some of the characteristics of a hospital bed," says Todd.

"These beds may have features such as height-adjustment mechanisms or adjustable positions for the back and knee, or be fitted with snap-on rails. But they're not regulated by FDA."

She says that such beds fall under the jurisdiction of the U.S. Consumer Product Safety Commission. "If these beds are used with any type of rail, consumers should adhere to the same safety recommendations in place for hospital beds." 

This article appears on FDA's Consumer Update page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm) which features the latest on all FDA-regulated products.

For More Information

Hospital Bed Safety
www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/default.htm

Preventing hospital bed fires
www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062151.htm

Safety Brochure: Bed Rails in Hospitals, Nursing Homes, and Home Health Care
www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/ucm125857.pdf

MedWatch, for reporting adverse events
www.fda.gov/Safety/MedWatch/default.htm